

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|--|----------------------|---------------------|------------------|--|
| 10/789,303 | 02/26/2004 | Kelly Reed Clark | 28335/40012 | 8089 | |
| 4743 MARSHALL | 7590 04/20/2007 GERSTEIN & BORLIN I | EXAMINER | | | |
| MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | BURKHART, MICHAEL D | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1633 | | |
| | | | | | |
| | | | MAIL DATE | DELIVERY MODE | |
| | | | 04/20/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|---------------------|--------------|--|
| 10/789,303 | CLARK ET AL. | |
| Examiner | Art Unit | |
| Michael D. Burkhart | 1633 | |

| | | Air Oine | |
|---|--|--|--|
| | Michael D. Burkhart | 1633 | |
| The MAILING DATE of this communication appe | ars on the cover sheet with the c | orrespondence add | ress |
| THE REPLY FILED 26 March 2007 FAILS TO PLACE THIS AP | PLICATION IN CONDITION FOR A | ALLOWANCE. | |
| The reply was filed after a final rejection, but prior to or on this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a No a Request for Continued Examination (RCE) in compliance time periods: The period for reply expires 3 months from the mailing date | wing replies: (1) an amendment, aff otice of Appeal (with appeal fee) in o ce with 37 CFR 1.114. The reply mu | idavit, or other evider compliance with 37 C | nce, which FR 41.31; or (3) |
| b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire is | Advisory Action, or (2) the date set forth ater than SIX MONTHS from the mailing | g date of the final rejecti | on. |
| Examiner Note: If box 1 is checked, check either box (a) or of TWO MONTHS OF THE FINAL REJECTION. See MPEP 7 | 06.07(f). | | |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of ex under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b) NOTICE OF APPEAL | tension and the corresponding amount shortened statutory period for reply orig r than three months after the mailing da | of the fee. The approprinally set in the final Offi | iate extension fee ce action: or (2) as |
| The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exte a Notice of Appeal has been filed, any reply must be filed AMENDMENTS | nsion thereof (37 CFR 41.37(e)), to | avoid dismissal of th | ns of the date of e appeal. Since |
| 3. The proposed amendment(s) filed after a final rejection, (a) They raise new issues that would require further co (b) They raise the issue of new matter (see NOTE belo | nsideration and/or search (see NO ow); | TE below); | |
| (c) ☐ They are not deemed to place the application in befappeal; and/or (d) ☐ They present additional claims without canceling a | | | the issues for |
| NOTE: <u>See continuation sheet</u> . (See 37 CFR 1.11 | | cotca ciairris. | |
| 4. The amendments are not in compliance with 37 CFR 1.1 | | mpliant Amendment | (PTOL-324). |
| 5. Applicant's reply has overcome the following rejection(s) | | · | , |
| Newly proposed or amended claim(s) would be al non-allowable claim(s). | · | | _ |
| For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is protected. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: 19. Claim(s) rejected: 1-14, 18 and 21-38. Claim(s) withdrawn from consideration: | ⊠ will not be entered, or b) □ will vided below or appended. | ll be entered and an e | explanation of |
| AFFIDAVIT OR OTHER EVIDENCE | | | |
| The affidavit or other evidence filed after a final action, bu because applicant failed to provide a showing of good an was not earlier presented. See 37 CFR 1.116(e). | at before or on the date of filing a North date of the affidate of the affidat | otice of Appeal will <u>no</u> rit or other evidence is | ot be entered s necessary and |
| 9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to of showing a good and sufficient reasons why it is necessary | overcome <u>all</u> rejections under apper y and was not earlier presented. S | al and/or appellant fa ee 37 CFR 41.33(d)(| ils to provide a 1). |
| The affidavit or other evidence is entered. An explanatio REQUEST FOR RECONSIDERATION/OTHER | n of the status of the claims after e | ntry is below or attach | ned. |
| The request for reconsideration has been considered but See continuation sheet. | | n condition for allowa | nce because: |
| 12. ☐ Note the attached Information Disclosure Statement(s). 13. ☐ Other: See continuation sheet. | (PTO/SB/08) Paper No(s). | | |
| | | | |

Page 2

Continuation Sheet

3(a) Claim 1 has been amended to recite that AAV Rep 78 and 68 proteins are expressed at the level when under control of the p5 promoter, as opposed to the previous claim scope, which included expression of the Rep 78 and 68 proteins at about the level when under control of the p5 promoter. This narrowing limitation was not previously recited in the claims. Therefore, this limitation requires re-evaluation of the art of record, a new search to determine if the new claim scope is taught in the prior art, and consideration of the specification for support for the new limitation. Claim 1 has been further amended to recite that the Rep 52 and 40 proteins are overexpressed in comparison to expression when under control of the AAV p19 promoter. This limitation was not previously recited in the claims. Therefore, this limitation requires re-evaluation of the art of record, a new search to determine if the new claim scope is taught in the prior art, and consideration of the specification for support for the new limitation.

Claims 3 and 10 have been amended to recite that AAV helper functions are provided by infecting a cell with a helper virus of AAV or by expressing helper virus proteins in the cell.

These are limitations not previously recited in the claims. Therefore, the limitations require reevaluation of the art of record, a new search to determine if the new claim scope is taught in the prior art, and consideration of the specification for support for the new limitation.

Claim 9 has been amended to recite that the Ad SV-20 retains the ability to introduce an expression cassette encoding AAV Rep 52 and 40 into the cell. This limitation was not previously recited in the claims. Therefore, the limitation requires re-evaluation of the art of

Application/Control Number: 10/789,303

Art Unit: 1633

record, a new search to determine if the new claim scope is taught in the prior art, and

consideration of the specification for support for the new limitation.

11. All of applicant's arguments are directed to the amended claims. Because the amendments

have not been entered, these arguments are moot.

13. Although previously indicated as allowable, Claim 19 is objected to as being

dependent upon a rejected base claim, but would be allowable if rewritten in independent form

including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart

Examiner

Art Unit 1633 Sistt D. Pruke

SCOTT D. PRIEBE, PH.D. PRIMARY EXAMINER

Page 3